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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/888,079	06/22/2001	Signe Erickson Varner	55821 (71699)	6574

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EXAMINER
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DESANTO, MATTHEW F

ART UNIT	PAPER NUMBER
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3763

DATE MAILED: 10/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>		<b>Applicant(s)</b>	
	09/888,079		VARNER ET AL.	
	<b>Examiner</b>		<b>Art Unit</b>	
	Matthew F. DeSanto		3763	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 10 July 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 23-35, 41-47 and 49-79 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 23-35, 41-47 and 49-79 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Drawings*

1. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the angle of the cannula with respect to the piercing member, but more specifically the second angle must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

### *Claim Rejections - 35 USC § 102*

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

Art Unit: 3763

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 23, 24, 27-31, 38, 49, 51, 52, 54, 60, 61, 63, 64, 65, 67, 79 are rejected under 35 U.S.C. 102(e) as being anticipated by Palasis et al. (USPN 6,969,371).

Palasis et al. discloses the use of a medical device for treating the eye (see claims 1, 2, 6, 10) and having a piercing member (30) and a cannula (26) that administers a fluid into the body (see figure 6C, claims 2, 10 and entire reference)

4. Claims 23, 26, 27, 35, 38, 45, 47, 49, 50, 51, 56, 58, 59, 60-63, 70 – 79 are rejected under 35 U.S.C. 102(e) as being anticipated by Lo Russo (US 2002/133184).

Lo Russo discloses a method of performing surgery on the eyes with using an incision, wherein the device has a piercing member (258) and a cannula (214), wherein the piercing member pierces the eye and the cannula is advanced to the treatment site to remove a cataract or the like (Figure 4a, 4b and entire reference).

### ***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

Art Unit: 3763

having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 25, 32-34, 41, 48, 53, 55, 57, 62, 66, 68-78, 79 are rejected under 35 U.S.C.

103(a) as being unpatentable over Palasis et al. and further in view of Paques et al. (US Pub 2003/0171722) view of Bowman et al. (USPN 6,378,526).

Palasis et al. discloses the claimed invention except for what specific therapeutic agents can be applied to the eye as well as the specific location of wherein the eye the method will be used.

Paques et al. discloses a method for treating an eye with a device comprising a piercing member (4) with an outer diameter less than 25 gauge (0053) allowing the puncture location to self-seal and having a flexible plastic tube therein (0087) to administer a therapeutic substance to the eye. The device is used to treat conditions such as vascular occlusion (0039) by advancing the device transconjunctively and piercing the sclera of the eye and delivering a therapeutic agent subretinally (Figure 1, 2, 3 and paragraph [0105]-[0113]). Paques et al. also teaches more specific methods of injecting fluid into the eye.

Bowman et al., teaches a device for delivery of a therapeutic agent such as steroids, genetic material, or pharmaceuticals to the eye.

Therefore, it would have been obvious to one skilled in the art at the time of the invention to deliver follow the steps of Paques et al. when injecting fluid into the eye when performing retina surgery, as well as using several of the different therapeutic agents that are taught by Paques et al. and Bowman et al., since this is well known in the art to use different doses and medications depending on the procedure and treatment. The applicant specification also discloses several well known methods of treatment for the eye, which deal with therapeutic agents being infused into the eye (see page 1 and 2).

*Response to Arguments*

7. Applicant's arguments filed 5/23/06 have been fully considered and are persuasive. Therefore the past the 102 and 103 Rejections in view of Cupler, II (USPN 4,002,169) are withdrawn because of the arguments given in the remarks section.

8. The arguments drawn to Palasis et al. are not persuasive because Palasis et al. shows a lumen for the piercing member in figure 4 and figure 5. Palasis et al. has to have a lumen in order for the cannulas to move from an unexposed position to an exposed position. Palasis et al. also discloses using the specific device in the eye, therefore fulfilling the independent claim language on the basis of inherence since the device would have to pierce the outer eye surface and then the cannula would have to pierce the treatment site. The examiner makes a 103 rejection when the claims deal with specific location of the treatment cite.

*Conclusion*

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Yu et al. 6,544,249.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew F. DeSanto whose telephone number is 571-272-4957. The examiner can normally be reached on Monday-Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick LUCCHESI can be reached on (571) 272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Matthew DeSanto  
Art Unit 3763  
September 21, 2006